

EXHIBIT 1

PART 8

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more" continuation or continuation-in-part application of an application that was filed prior to the publication date of this final rule in the *Federal Register* without a petition and showing, and to file (at least) "one more" divisional application in compliance with § 1.78(d)(1)(ii) of an application that was filed prior to the effective date of this final rule without a petition and showing. The Office published the *Continuing Applications Proposed Rule* and the *Claims Proposed Rule* in the *Federal Register* on January 3, 2006, which set forth proposed changes to the practice for continued examination filings, patent applications containing patentably indistinct claims, and examination of claims in patent applications. Applicants have been provided with a time period of more than one and a half years from the publication date of the proposed rules to the effective date of this final rule, and a time period of more than sixty days from the publication of the final rule to the effective date. Therefore, applicants should have sufficient advance notice of the rule changes.

Comment 335: One comment suggested a transitional practice for divisional applications, permitting benefit claims to be added only to applications filed on or before the effective date in serial divisional applications.

Response: Section 1.78(d)(1)(ii) as adopted in this final rule permits an applicant to file a divisional application of an application for the claims to a non-elected invention that has not been examined if the application was subject to a requirement for restriction. The divisional application need not be filed during the pendency of the application subject to a requirement for restriction, as long as the copendency requirement of 35 U.S.C. 120 is met. Thus, applicant may file the divisional application during the pendency of the application that was subject to a requirement for restriction or the pendency of any continuing application of such an application.

Comment 336: A number of comments suggested that the changes to § 1.75 should apply only to applications filed on or after the effective date. A number of comments disagreed with the Office's decision to apply the changes to § 1.75 to applications filed before the effective date. Several comments further argued that the cost of "retroactively" applying the rule changes would be enormous to applicants, especially to small entities, because most applicants would be required to review their pending applications for compliance with the new requirement. Several

comments estimated the cost to be 100 to 120 million dollars to designate representative claims in pending applications, and one comment estimated the cost to be 180 million dollars. Several comments argued that small entities are less able to absorb expenses associated with reviewing and revising pending applications. This could prevent small entities from prosecuting pending applications. Several comments argued that because applicants already paid the increased claims fees under the Consolidated Appropriations Act, 2005, in the pending applications for the Office to examine all of the claims, the new requirements would constitute a taking by the Federal Government. Several comments also argued that applicants did not anticipate the additional costs in reviewing and amending the applications for compliance with the new requirements.

Response: The Office has revised § 1.75 to provide that if an application contains more than five independent claims or more than twenty-five total claims, the applicant must submit an examination support document in compliance with § 1.265. Of the applications currently awaiting examination for which claim data is available in PALM (which is over ninety percent of the applications for which preexamination processing is complete), about thirty percent contain more than five independent claims or more than twenty-five total claims. Therefore, the Office's decision to grandfather only pending applications in which a first Office action on the merits was mailed before November 1, 2007 (the effective date of the changes in this final rule) with respect to the changes to § 1.75 will not affect the majority of applications that are currently pending before the Office. In addition, the changes in this final rule do not preclude an applicant from filing an application or obtaining a patent containing any number of claims, but simply changes the procedures for applications containing more than five independent claims or more than twenty-five total claims. Therefore, there is no support for the proposition that the changes in this final rule amount to a "taking" by the government. Additionally, § 1.117 as adopted in this final rule provides that if an amendment canceling a claim is filed before an examination on the merits has been made of the application, the applicant may request a refund of any excess claims fee paid on or after December 8, 2004 (fees paid under the

Consolidated Appropriations Act), for such claim.

Comment 337: One comment suggested that if the changes to § 1.75 are retroactively applied to applications filed before the effective date, the Office should automatically consider certain claims as representative when applicant fails to designate claims within the time period set forth in a notice requiring the designation of representative claims. One comment inquired about requiring applicants to take action on applications in the backlog within the first month following enactment of the proposed rules. One comment suggested that the Office should send a notice giving applicant three months (extendable to six months) within which to designate the representative claims in each pending application and, if necessary, to file an examination support document.

Response: As discussed previously, this final rule does not adopt the "representative claims" examination approach. Under this final rule, applicant is permitted to present more than five independent claims or more than twenty-five total claims if applicant files an examination support document before a first Office action on the merits of an application. The Office does not expect that most applicants will need to take any action to comply with the changes to § 1.75 in this final rule within the first month following the effective date of this final rule because the majority of applications contain five or fewer independent claims and twenty-five or fewer total claims. The Office will provide an applicant who filed a nonprovisional application under 35 U.S.C. 111(a) before November 1, 2007, or a nonprovisional application that entered the national stage after compliance with 35 U.S.C. 37 before November 1, 2007, and who would be affected by the changes in the final rule, with an opportunity to submit: (1) An examination support document; (2) a new set of claims such that the application contains five or fewer independent claims and twenty-five or fewer total claims; or (3) a suggested restriction requirement. Specifically, the Office will issue a notice setting a two-month time period that is extendable under § 1.136(a) or (b) within which the applicant must exercise one of these options in order to avoid abandonment of the application. The Office, however, may combine such a notice with a requirement for restriction, in which case the applicant must make an election responsive to the restriction requirement and, if there are more than five independent claims or more than twenty-five total claims drawn to the elected invention, the applicant must

also: (1) File an examination support document in compliance with § 1.265; or (2) amend the application such that it contains five or fewer independent claims and twenty-five or fewer total claims drawn to the elected invention. Thus, if such a notice is combined with a requirement for restriction, the applicant does not have the option of replying to such notice with a suggested restriction requirement under § 1.142(c).

M. Miscellaneous

Comment 338: One comment suggested that the changes to § 1.78 are contrary to the purpose of the Bayh-Dole Act.

Response: The Bayh-Dole University and Small Business Patent Procedures Act (Pub. L. 96-517, 94 Stat. 3015-28 (codified at 35 U.S.C. 200 *et seq.*)), concerns patent rights in inventions made with federal assistance. Specifically, 35 U.S.C. 200 provides that:

It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.

The changes to § 1.78 adopted in this final rule do not concern patent rights in inventions made with federal assistance and do not impinge upon any of the policies or objectives set forth in 35 U.S.C. 200. The changes in this final rule do not treat patent applications resulting from federally supported research differently from other patent applications. The policy objectives of the Bayh-Dole Act do not encourage or condone more favorable treatment of patent applications resulting from federally supported research. See *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 929, 69 U.S.P.Q.2d 1886, 1896 (Fed. Cir. 2004) (none of the eight policy objectives of the Bayh-Dole Act encourages or condones less stringent application of the patent laws to universities than to other entities).

Comment 339: A number of comments suggested that to help reduce the backlog of pending applications the Office should provide a procedure under which an applicant may request deferral of examination of the application.

Response: The rules of practice currently have a procedure under which an applicant may request deferral of examination. Specifically, § 1.103(d) permits deferral of examination for up to three years from the earliest filing date for which a benefit is claimed under title 35, United States Code. The Office publishes any application in which a deferral of examination under § 1.103(d) is requested. The entire period of deferral is a reduction under § 1.704(c)(1) of any patent term adjustment.

Comment 340: A number of comments suggested variations of the deferral of examination procedure under § 1.103(d), including, *inter alia*, providing for automatic deferral of examination, extending the period of deferral, allowing third party requests for examination of deferred applications, eliminating any negative impact on patent term adjustment resulting from deferral, adopting deferral of examination procedures used in other countries such as Japan and Canada, tying the period of deferral to the actual filing date of the application rather than the claimed benefit date, and establishing deferral fees based on the length of deferral.

Response: The deferral of examination procedure set forth in § 1.103(d) was used in fewer than two hundred applications since November 29, 2000 (the effective date of § 1.103(d)). The Office did not propose any changes to the deferral of examination procedure in the notices of proposed rulemaking published on January 3, 2006, in the *Federal Register*. In view of the comments received on the deferral of examination procedure, the Office is studying whether changes (*e.g.*, the maximum deferral period, third party request for examination, and patent term adjustment) to the deferral of examination procedure would be appropriate.

Comment 341: Several comments opposed third party participation, but suggested that the Office could move toward providing a post-grant opposition period, similar to that currently offered in Europe, during which the public could oppose issued patents and make prior art submissions so the patent could receive a post-grant review.

Response: Legislation regarding post-grant opposition and related

participation by third parties is currently pending before Congress. If enacted, the Office will implement the legislation accordingly.

Comment 342: A number of comments suggested expanding the opportunity under § 1.99 for third parties to submit prior art references in applications; for example, up to a first Office action.

Response: The Office has proposed changes to § 1.99 that would extend the period for submission of information from two months after pre-grant publication of the application to six months after pre-grant publication of the application, or mailing of a notice of allowance, whichever occurs first. See *Changes To Information Disclosure Statement Requirements and Other Related Matters*, 71 FR at 38816, 38822, 1309 Off. Gaz. Pat. Office at 31, 36.

Comment 343: One comment questioned applicant's recourse if a third party submission was filed in his or her application.

Response: Applicant's recourse would be the same as it currently is when a third party submits patents or publications pursuant to § 1.99 in a published patent application. Applicant will have an opportunity to comment on any patents or publications relied upon by the examiner in a rejection of applicant's claims. Note, however, 35 U.S.C. 122(c) prohibits third party protests.

Comment 344: Several comments suggested that prior art submissions by third parties should be required to conform to current information disclosure statement rules. These comments also suggested that either statements of relevance for each submitted document, or arguments why the claims are unpatentable in view of the cited documents, should accompany the submissions.

Response: Prior to the publication of a patent application, a third party may file prior art submissions in compliance with the requirements of § 1.291 in the application. After the publication of the application, § 1.99 only permits a third party to file up to ten patents or publications per submission. Section 1.99 does not permit the third party to file comments regarding the documents, or comments regarding the patentability of the claims in view of the documents. Additionally, permitting a third party to file an explanation of relevance would rise to the level of a protest, which is prohibited by 35 U.S.C. 122(c).

Comment 345: Several comments suggested allowing a third party to request examination of an application upon paying a fee during a time frame such as between thirty-six and forty-

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eight months from the application filing date. One comment suggested permitting third parties to request accelerated examination of long-pending applications by submitting documents required for accelerated examination.

Response: Under the current patent laws and regulations, it is not proper for a third party to be involved in the examination of an application owned by another which includes seeking to accelerate the examination of an application that is properly awaiting its turn to be examined. Permitting a third party to advance prosecution of an application may be considered in the future for those instances in which an applicant has requested deferral of the examination. However, at this time, the Office has not elected to amend § 1.103(d) to permit such action, in order to further study the issue and to provide the public additional opportunity to comment.

Comment 346: One comment suggested the use of authorized third party prior art searches.

Response: Patents or publications filed by a third party in compliance with § 1.99 may be entered in the file of a published application. Examiners may use any of these references in a rejection, if appropriate.

Comment 347: Several comments were critical of the Office's position that the proposed changes to the practice for continuing applications, request for continued examination, and applications containing patentably indistinct claims will not create any additional work for the applicant.

Response: The changes being adopted in this final rule will not require any additional submissions for the majority of patent applications. Prosecution, however, may be more compact since the number of continuing applications and requests for continued examination permitted without any justification is being limited. Nevertheless, the changes being adopted in this final rule will result in more effective and efficient examination without any additional work on the part of the majority of applicants.

Comment 348: Several comments recommended that the Office should conduct a public hearing before adopting the rule changes. One comment suggested that the Office should issue a green paper or advance notice of proposed rule making to receive more input and perform a cost-benefit analysis on the rule changes. One comment recommended that the Office should form a patent practice advisory committee, consisting of volunteers from the patent bar, for the

purpose of studying problems experienced by the Office and proposing solutions that would be tailored to address those problems. The comments recommended that the Office should bring together all the relevant parties, including the Office, patent practitioners, patentees, litigators, and judges, to arrive at a solution that benefits all parties in the patent system.

Response: 35 U.S.C. 2(b)(2)(B) directs the Office to follow the procedures set forth in 5 U.S.C. 553 in adopting changes to the rules of practice, and 35 U.S.C. 3(a)(2)(B) directs the Office to consult with the Patent Public Advisory Committee when proposing or adopting changes to the rules of practice that change user fees or are subject to notice and comment under 5 U.S.C. 553. The Office published notices of proposed rule making pursuant to 5 U.S.C. 553(b) in advance of this final rule, provided an extended comment period to give interested persons an opportunity to submit written data, views, or arguments pursuant to 5 U.S.C. 553(c), and has published this final rule at least thirty days in advance of its effective date pursuant to 5 U.S.C. 553(d). The Office also consulted with the Patent Public Advisory Committee prior to publishing the notices of proposed rule making and this final rule. The Office also conducted four public meetings to obtain feedback from the public on the proposed changes which resulted in the changes being adopted in this final rule: (1) The first in Chicago, Illinois, on February 1, 2006; (2) the second in Berkeley, California, on February 28, 2006; (3) the third in Houston, Texas, on March 22, 2006; and (4) the fourth in Alexandria, Virginia (at the Office's Carlyle campus) on April 25, 2006. The number of comments submitted in response to the notices of proposed rule making indicates that interested persons and organizations have been given ample opportunity to provide input on the changes being adopted in this final rule.

IV. Rule Making Considerations

A. Administrative Procedure Act

This notice adopts changes to the rules of practice that concern the process for applying for a patent, namely, continuing applications and requests for continued examination practices, the treatment of applications containing more than a set number of independent or total claims, and the treatment of multiple applications containing patentably indistinct claims. The changes being adopted in this notice do not change the substantive criteria of patentability and do not

effectively foreclose the applicant's opportunity to make a case on the merits (*i.e.*, the changes being adopted in this final rule continue to provide patent applicants with numerous opportunities). Therefore, these rule changes involve interpretive rules, or rules of agency practice and procedure. See *Bachow Communs., Inc. v. FCC*, 237 F.3d 683, 690 (DC Cir. 2001) (rules governing an application process are "rules of agency organization, procedure, or practice" and exempt from the Administrative Procedure Act's notice and comment requirement); see also *Fressola v. Manbeck*, 36 USPQ2d 1211, 1215 (D.D.C. 1995) ("it is extremely doubtful whether any of the rules formulated to govern patent or trade-mark practice are other than 'interpretive rules, general statements of policy, * * * procedure, or practice.'") (quoting C.W. Ooms, *The United States Patent Office and the Administrative Procedure Act*, 38 Trademark Rep. 149, 153 (1948)). Accordingly, prior notice and an opportunity for public comment were not required pursuant to 5 U.S.C. 553(b)(A) (or any other law), and thirty-day advance publication is not required pursuant to 5 U.S.C. 553(d) (or any other law). Nevertheless, the Office sought public comment on proposed changes to these rules of practice to obtain the benefit of such input prior to adopting the changes to the rules of practice in this final rule.

B. Regulatory Flexibility Act

As prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553 (or any other law), neither a regulatory flexibility analysis nor a certification under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are required. See 5 U.S.C. 603. Nevertheless, the Office published notices of proposed rule making setting forth the factual basis for certification under the Regulatory Flexibility Act and sought public comment on that certification. See *Changes to Practice for the Examination of Claims in Patent Applications*, 71 FR at 66, 1302 Off. Gaz. Pat. Office at 1333, and *Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims*, 71 FR at 56–57, 1302 Off. Gaz. Pat. Office at 1325. For the reasons set forth herein, the Deputy General Counsel for General Law of the United States Patent and Trademark Office has certified to the Chief Counsel for Advocacy of the Small Business Administration that the changes in this final rule will not have a significant economic impact on a

substantial number of small entities. See 5 U.S.C. 605(b).

This final rule provides that: (1) A third or subsequent continuation or continuation-in-part application or any second or subsequent request for continued examination must include a showing as to why the amendment, argument, or evidence sought to be entered could not have been submitted prior to the close of prosecution after a first and second continuation or continuation-in-part application and a request for continued examination; (2) any divisional application be the result of a requirement to comply with the requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121 in the prior-filed application; (3) an application that contains or is amended to contain more than five independent claims or more than twenty-five total claims must include an examination support document under 37 CFR 1.265 that covers each claim (whether in independent or dependent form) before the first Office action on the merits; and (4) multiple applications that have the same claimed filing or priority date, substantial overlapping disclosure, a common inventor, and a common assignee include either an explanation as to how the claims are patentably distinct, or a terminal disclaimer and explanation as to why patentably indistinct claims have been filed in multiple applications.

In response to the Office's certification in the notices of proposed rule making, the Small Business Administration Office of Advocacy (SBA-Advocacy) submitted a comment contending that the proposed changes are likely to have a significant economic impact on a substantial number of small entities, including small businesses and small independent inventors. SBA-Advocacy recommended that the Office conduct a supplemental Initial Regulatory Flexibility Analysis before publishing a final rule.

The Office's analysis of the proposed rules indicated that the rules would not have a significant economic impact on a substantial number of small entities. The Office considered all public comments addressing small entities, including those submitted by SBA-Advocacy. In response to these comments, this final rule incorporates a number of revisions designed to further reduce the number of small entities affected by the changes and the impacts on small entities. These changes in this final rule vis-à-vis the proposed rules that reduce small entity impacts are as follows: (1) This final rule adopts an examination support document

requirement threshold of five independent claims or twenty-five total claims, rather than ten representative claims; (2) this final rule provides that small entities as defined by the Regulatory Flexibility Act are exempt from the requirement that an examination support document must, for each cited reference, include an identification of all of the limitations of each of the claims that are disclosed by the reference; (3) this final rule adopts a continued examination filing petition threshold of two continuing applications (continuation or continuation-in-part applications), plus a request for continued examination in any one of the initial or two continuing applications, rather than one continuation application, continuation-in-part application, or request for continued examination; (4) this final rule does not require that a divisional application be filed during pendency of initial application; and (5) this final rule provides for at least "one more" continuation or continuation-in-part application after the effective date, regardless of the number of previous continued examination filings.

In addition, the Office commissioned a detailed analysis of the impacts of this final rule on small entities. The analysis concludes that this final rule is not expected to result in a significant economic impact on a substantial number of small entities. The analysis measured economic impact in terms of annualized incremental cost as a percentage of revenue. The analysis indicated that the incremental cost (not annualized) would be between \$2,563 and \$13,121 for an entity who would be required to file an examination support document, a petition for an additional continued examination filing, or both. The analysis presumed that an economic impact greater than three percent of annualized incremental cost as a percentage of revenue was a significant impact. The analysis indicated that no small entities fell into this category. The analysis also presumed that an economic impact greater than one percent of annualized incremental cost as a percentage of revenue was a more moderate impact. The analysis indicated that fewer than one percent of small entities fell into this category. The analysis also presumed that a substantial number of small entities are affected if more than twenty percent of small entities are impacted. The analysis indicated that about 1.0 percent of small entities would be affected by the requirement to submit an examination support document, that about 2.7 percent of

small entities would be affected by the requirement to submit a petition for an additional continued examination filing, and that about 0.3 percent of small entities would be affected by both the requirement to submit an examination support document and the requirement to submit a petition for an additional continued examination filing. A copy of the report containing this analysis is available on the Office's Internet Web site at <http://www.uspto.gov>.

As a result of this analysis, the Office has determined that it is appropriate to make a certification that the changes being adopted in this final rule would not have a significant economic impact on a substantial number of small entities. The Office has revised the final rule requirements, as discussed previously, to further reduce economic impacts on small entities.

SBA-Advocacy commented that while the Office asserts that preparation of the examination support document should cost about \$2,500, small entities contend that completing an examination support document will be more costly, time consuming and restrict their ability to prosecute patents vigorously. SBA-Advocacy also commented that small entity representatives have provided feedback that completion of an examination support document could cost from \$25,000 to \$30,000.

The Claims Proposed Rule referenced a \$2,500 figure covering a patent novelty search, analysis, and opinion, as reported in a 2003 survey conducted by the American Intellectual Property Law Association (AIPLA). The Office agrees with the comments that this figure is probably less than the cost of an examination support document in most situations. Therefore, the Office has further analyzed costs based on the modified examination support document requirements applicable to small entities. The analysis models cost variability based on the number of claims the examination support document must address, and on whether or not a prior art search was conducted when the application was prepared. Based on this analysis, the Office estimates that the examination support document costs for small entities will range from \$2,563 up to \$13,121, although this latter figure assumes the examination support document must address as many as fifty independent claims or three hundred and fifty total claims. Only a small number of small entities, however, will be required to prepare an examination support document, and nearly all of these will incur costs towards the lower end of the range. Thus, the Office does not expect the final rule to result in a

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significant impact on a substantial number of small entities.

SBA-Advocacy commented that small entity representatives have asserted that, taken together, the two proposed changes would increase the cost of application preparation and hinder the patent prosecution process.

As discussed previously, the Office commissioned a detailed analysis of the impact of the final rule on small entities. The analysis explicitly considered the combined cost of both proposed rules (which have been combined into a single final rule). The analysis concludes that the final rule is not expected to result in a significant economic impact on a substantial number of small entities.

SBA-Advocacy commented that small entity representatives have raised concerns that the proposed changes will significantly impact the most valuable and commercially viable patents because those types of patents typically involved a higher number of continuations.

The Office notes that there are studies espousing the position that many commercially valuable patents are the result of a continuing application, or of a second or subsequent continuing application. However, these studies do not support the position that the applicants could not have obtained these commercially valuable patents but for the availability of an unlimited number of continuing applications. That is, these studies do not show that these commercially valuable patents could not have been obtained via two or fewer continuing applications prosecuted with a reasonable amount of foresight and diligence. Thus, these studies do not demonstrate that these commercially valuable patents happen to be the result of a continuing application or of multiple continuing applications for any reason other than simply because the prosecution tactics employed in the applications underlying these patents were based upon the availability of an unlimited number of continuing applications.

The analysis commissioned by the Office specifically considered the claim that the most valuable and commercially viable patents are those types of patents that typically involved a higher number of continuations. The Office ultimately rejected the claim that this final rule will preclude applicants from being able to obtain a patent on the most valuable and commercially viable patents due to the speculative nature of the nexus drawn between the availability of an unlimited number of continuing applications and an

applicant's ability to obtain these commercially valuable patents.

SBA-Advocacy commented that small entity representatives have indicated that limiting applicants to ten representative claims would make it very difficult to properly identify a potential patent, could create future liability concerns, and would weaken potential patents.

The final rule requirements apply to patent applications with more than five independent claims or more than twenty-five total claims, rather than ten representative claims. As discussed previously, applicants with more than five but less than fifteen independent claims, or more than twenty-five but less than seventy-five total claims, to an invention are able to prosecute their application in a manner that does not trigger the claims or continuations requirements. Specifically, an applicant may do this by submitting an initial application containing up to five independent claims and up to twenty-five total claims, and then adding a similar number of claims in each of two continuation applications (or two continuation-in-part applications, or one continuation application and one continuation-in-part application) permitted without a petition. Moreover, even for those applications that will require an examination support document, the requirement does not "limit" applicants to any particular number of claims. Applicants may continue to submit as many claims as necessary to appropriately claim their inventions, even if doing so required them to prepare and submit an examination support document.

SBA-Advocacy commented that small entity representatives have contended that limiting continuation applications and examinations would inhibit their ability to enhance their applications, significantly increase costs through new fees, and force small entities to seek review through the very expensive appeals process. Small entity representatives thus assert that limiting the number of continuations could severely weaken small entities' ability to protect their patents.

The Office analysis indicates that the continued examination filing requirements adopted in this final rule will not lead to significant cost increases nor will it have a significant economic impact on a substantial number of small entities. The requirements are necessary to ensure that patent applications are of reasonable quality and that applicants pursue their patents in good faith. The excessive use of continued examination filings has been a major factor in the

growing backlog of unexamined applications. With respect to having to use the appeals process in place of additional continued examination filings, if an applicant disagrees with the examiner's rejections, the applicant should file an appeal rather than filing a continuation application or a request for continued examination, for reasons discussed in detail in the statement of considerations for the final rule. The Office believes that applicants should have sufficient opportunity to place the application in condition for appeal during the prosecution of the initial application, two continuing applications, and a request for continued examination with a petition showing why the amendment, argument, or evidence sought to be entered could not have been previously submitted.

SBA-Advocacy commented that the proposed changes will affect a substantial number of small entities, and that the two proposed changes to the rules reshape the basic rights of any small entity that files a patent application.

The Office agrees that the final rule places new requirements on the current patent application process. However, the Office's analysis indicates that the rule will not have a significant economic impact on a substantial number of small entities. In fact, only a small proportion of small entities will be affected by the changes in this final rule.

SBA-Advocacy commented that small entity representatives have contended that the definition of small entity that the Office uses in its certification is for calculating filing fees and excludes any small entity that has a contractual arrangement involving the invention with a larger company. SBA-Advocacy commented that small entity representatives have further asserted that small business size standards for Regulatory Flexibility Act purposes do not include this restriction so the number of small businesses affected is likely to be larger than stated in the certification.

The Regulatory Flexibility Act permits an agency head to establish, for purposes of Regulatory Flexibility Act analysis and certification, one or more definitions of "small business concern" that are appropriate to the activities of the agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment. See 5

U.S.C. 601(3) and 13 CFR 121.903(c). Pursuant to this authority, the Office has established the following definition of small business concern for purposes of the Office conducting an analysis or making a certification under the Regulatory Flexibility Act for patent-related regulations: A small business concern for Regulatory Flexibility Act purposes for patent-related regulations is a business or other concern that: (1) Meets the Small Business Administration's definition of a "business concern or concern" set forth in 13 CFR 121.105; and (2) meets the size standards set forth in 13 CFR 121.802 for the purpose of paying reduced patent fees, namely, an entity: (a) Whose number of employees, including affiliates, does not exceed 500 persons; and (b) which has not assigned, granted, conveyed, or licensed (and is under no obligation to do so) any rights in the invention to any person who made it and could not be classified as an independent inventor, or to any concern which would not qualify as a non-profit organization or a small business concern under this definition. See *Business Size Standard for Purposes of United States Patent and Trademark Office Regulatory Flexibility Analysis for Patent-Related Regulations*, 71 FR 67109, 67112 (Nov. 20, 2006), 1313 Off. Gaz. Pat. Office 60, 63 (Dec. 12, 2006) (notice). Prior to establishing this definition of small business concern for purposes of the Office conducting an analysis or making a certification under the Regulatory Flexibility Act for patent-related regulations, the Office consulted with the Small Business Administration Office of Advocacy and published such a definition for public comment. See *Size Standard for Purposes of United States Patent and Trademark Office Regulatory Flexibility Analysis for Patent-Related Regulations*, 71 FR 38388 (Jul. 6, 2006), 1309 Off. Gaz. Pat. Office 37 (Aug. 1, 2006) (notice). The Small Business Administration small entity size standards set forth in 13 CFR 121.802 excludes any business concern that has assigned, granted, conveyed, or licensed any rights in the invention to an entity which would not qualify for small entity status.

Nevertheless, in analyzing the provisions of the final rule, the Office explicitly considered a sensitivity analysis that assumed all patent applicants qualified as small entities. Even under this sensitivity analysis, this final rule is not expected to result in a significant impact on a substantial number of small entities.

SBA-Advocacy suggested that with respect to the continued examination filing requirements, the Office should

increase the number of permissible continuing applications.

The final rule changes the continued examination filing petition threshold from a single continuation application, continuation-in-part application, or request for continued examination as proposed to two continuing applications (continuation or continuation-in-part applications), and a single request for continued examination in any one of the initial or two continuing applications.

SBA-Advocacy suggested that with respect to the continued examination filing requirement, the Office should consider increasing the fees for additional continuation applications.

Currently, patent application and excess claims fees are set by statute (35 U.S.C. 41(a)). In 2002, the Office proposed a patent fee structure that included a graduated excess claims fees schedule and additional fees for continued examination filings. As discussed previously, however, the Office was unable to garner sufficient support from patent user groups for a patent fee structure including a graduated excess claims fees schedule or any additional fees for continued examination filings. Therefore, the Office did not pursue this alternative.

SBA-Advocacy suggested that with respect to the continued examination filing requirement, the Office should defer review of subsequent continuation applications.

The Office considered expanding the deferral of examination provisions to allow a longer deferral of examination period. The Office currently has a provision (37 CFR 1.103(d)) under which an applicant may request deferral of examination for up to three years from the earliest filing date for which a benefit is claimed. As discussed previously, the Office is studying whether changes (e.g., the maximum deferral period, third party request for examination, and patent term adjustment) to the deferral of examination procedure would be appropriate.

SBA-Advocacy suggested that with respect to the claims requirements, the Office should expand the number of representative claims included in initial review.

The Office has revised the final rule to change the examination support document threshold from ten representative claims to five independent claims or twenty-five total claims. As discussed previously, however, applicants with more than five but less than fifteen independent claims, or more than twenty-five but less than seventy-five total claims, to an invention are able to prosecute their

application in a manner that does not trigger the claims or continuations requirements.

SBA-Advocacy suggested that with respect to the claims requirements, the Office should provide expedited review of applications that contain ten or fewer representative claims. The Office has considered the suggestion to provide expedited examination to applications containing less than a set number of claims. As discussed previously, the Office currently has an accelerated examination program for applicants who limit the number of claims in their applications (to no more than three independent claims and no more than twenty total claims) and who also provide an accelerated examination support document. Therefore, the Office did not pursue this alternative in the final rule.

SBA-Advocacy suggested that with respect to the claims requirements, the Office should not apply the regulation to the backlog of pending unexamined applications.

The Office has considered not applying the claims requirement to pending applications that have not yet been examined to minimize the impact on small entities. The examination support document threshold being adopted in this final rule (i.e., more than five independent claims or more than twenty-five total claims) means that most small entity applications will not be impacted by the final rule or the decision to apply the final rule to the backlog of unexamined applications. Given the current backlog of over 700,000 unexamined applications, a decision to not apply the changes to the backlog of unexamined applications would mean that it would be calendar year 2010 before the Office would see any benefit from the change, and that the Office (and applicants) would be in a transition state until late calendar year 2011. Therefore, this suggestion was not adopted in the final rule.

The Office also received a number of additional comments from the public generally asserting that the Office did not comply with the requirements of the Regulatory Flexibility Act in certifying that the changes in this rule making will not have a significant economic impact on a substantial number of small entities. The comments stated that: (1) In light of the fact that several large companies support the proposed changes it is questionable whether the rule changes are truly neutral towards small companies and that a bias in favor of large companies and against small entities could be in violation of the Regulatory Flexibility Act; (2) the Office's certification did not adequately

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address the impact of the proposed rules on small entities, and the Office failed to provide a credible factual basis to justify its certification that the proposed rules would not have a significant economic impact on a substantial number of small entities in compliance with 5 U.S.C. 605(b); (3) the rule changes would have a significant economic impact on a substantial number of small entities seeking patents due to the additional costs associated with preparing an application, establishing the required showing under 37 CFR 1.78(d)(1)(vi) and 1.114(g), and supplying an examination support document in compliance with 37 CFR 1.265, and would hinder the abilities of small entities to enhance their applications and protect their inventions; (4) the definition of small entities used by the Office in its certification of the proposed rules is for the purpose of paying reduced patent fees and excludes any application from a small business that has assigned, granted, conveyed, or licensed any rights in the invention to an entity which would not qualify for small entity status; (5) the Office should prepare an initial Regulatory Flexibility Analysis and republish the proposed rules before issuing any final rule to enable the Office to closely examine the impact on the affected small entities, encourage small entities to comment on additional information provided by the analysis, identify viable regulatory alternatives to the proposed rules, and demonstrate the Office's compliance with the Regulatory Flexibility Act; (6) the Office did not describe any viable alternatives to the proposed rules to provide regulatory relief to small entities as required under 5 U.S.C. 603(c); (7) the rule changes would be invalid and vulnerable to challenges under 5 U.S.C. 611 if the Office fails to comply with the requirements of the Regulatory Flexibility Act; and (8) the Office should exempt small entities from complying with the proposed rules to avoid further scrutiny under the Regulatory Flexibility Act.

The Office has received comments from some large entities that the changes being adopted in this final rule have a bias against large entities, and has received comments from small entities that the changes being adopted in this final rule have a bias in favor of large entities. The changes being adopted in this final rule are neutral towards both small entities and large entities. That several large entities support the changes being adopted in this final rule is more likely indicative of a willingness to take a systemic view

with respect to the need to take more significant steps to address patent quality and pendency.

As discussed previously, the Office commissioned a detailed analysis of the final rule's impact on small entities. As a result of this analysis, the Office has determined that it is appropriate to make a certification that the changes being adopted in this final rule would not have a significant economic impact on a substantial number of small entities. Therefore, the Office is not required to conduct a Regulatory Flexibility Analysis.

Pursuant to 5 U.S.C. 605(b), the requirements in 5 U.S.C. 603 and 604 for an initial and final Regulatory Flexibility Analysis (including identification of viable regulatory alternatives to the proposed rules) do not apply if the agency head certifies that the changes will not have a significant economic impact on a substantial number of small entities. In accordance with 5 U.S.C. 605(b), the Deputy General Counsel for General Law of the United States Patent and Trademark Office has certified to the Chief Counsel for Advocacy of the Small Business Administration that the proposed changes would not have a significant economic impact on a substantial number of small entities.

The Office considers this rule making to be in compliance with the requirements of the Regulatory Flexibility Act. Thus, the possibility of legal action does not warrant a decision to delay proceeding with the changes being adopted in this final rule to allow for preparation of an initial and final Regulatory Flexibility Analysis, or to completely exempt small entities from complying with the changes being adopted in this final rule.

C. Executive Order 13132 (Federalism)

This rule making does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

D. Executive Order 12866 (Regulatory Planning and Review)

This rule making has been determined to be significant for purposes of Executive Order 12866 (Sept. 30, 1993), as amended by Executive Order 13258 (Feb. 26, 2002) and Executive Order 13422 (Jan. 18, 2007).

E. Executive Order 13175 (Tribal Consultation)

This rule making will not: (1) Have substantial direct effects on one or more Indian tribes; (2) impose substantial direct compliance costs on Indian tribal

governments; or (3) preempt tribal law. Therefore, a tribal summary impact statement is not required under Executive Order 13175 (Nov. 6, 2000).

F. Executive Order 13211 (Energy Effects)

This rule making is not a significant energy action under Executive Order 13211 because this rule making is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under Executive Order 13211 (May 18, 2001).

G. Executive Order 12988 (Civil Justice Reform)

This rule making meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (Feb. 5, 1996).

H. Executive Order 13045 (Protection of Children)

This rule making is not an economically significant rule and does not concern an environmental risk to health or safety that may disproportionately affect children under Executive Order 13045 (Apr. 21, 1997).

I. Executive Order 12630 (Taking of Private Property)

This rule making will not effect a taking of private property or otherwise have taking implications under Executive Order 12630 (Mar. 15, 1988).

J. Congressional Review Act

Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), the United States Patent and Trademark Office will submit a report containing this final rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the Government Accountability Office. The changes in this final rule will not result in an annual effect on the economy of 100 million dollars or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this final rule is not a "major rule" as defined in 5 U.S.C. 804(2).

K. Unfunded Mandates Reform Act of 1995

The changes in this final rule will not result in the expenditure by State, local,

and tribal governments, in the aggregate, or by the private sector, of 100 million dollars or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. See 2 U.S.C. 1501 *et seq.*

L. National Environmental Policy Act

This rule making will not have any effect on the quality of environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. See 42 U.S.C. 4321 *et seq.*

M. National Technology Transfer and Advancement Act

The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) are inapplicable because this rule making does not contain provisions which involve the use of technical standards.

N. Paperwork Reduction Act

This final rule involves information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The collection of information involved in this final rule has been reviewed and approved by OMB under OMB control number 0651-0031. This final rule provides that: (1) A third or subsequent continuation or continuation-in-part application or any second or subsequent request for continued examination must include a showing that the amendment, argument, or evidence sought to be entered could not have been submitted prior to the close of prosecution after a first and second continuation or continuation-in-part application and a request for continued examination; (2) an application that contains or is amended to contain more than five independent claims or more than twenty-five total claims must include an examination support document under 37 CFR 1.265 that covers each claim (whether in independent or dependent form) before the issuance of a first Office action on the merits; and (3) multiple applications that have the same claimed filing or priority date, substantial overlapping disclosure, a common inventor, and a common assignee must include either an explanation of how the claims are patentably distinct, or a terminal disclaimer and explanation of why patentably indistinct claims have been filed in multiple applications. The United States Patent and Trademark

Office has resubmitted an information collection package to OMB for its review and approval because the changes in this notice do affect the information collection requirements associated with the information collection under OMB control number 0651-0031.

The title, description and respondent description of the information collection under OMB control number 0651-0031 is shown below with an estimate of the annual reporting burdens. Included in the estimate is the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB Number: 0651-0031.

Title: Patent Processing (Updating).

Form Numbers: PTO/SB/08, PTO/SB/17, PTO/SB/17p, PTO/SB/21-27, PTO/SB/24B, PTO/SB/30-32, PTO/SB/35-39, PTO/SB/42-43, PTO/SB/61-64, PTO/SB/64a, PTO/SB/67-68, PTO/SB/91-92, PTO/SB/96-97, PTO-2053-A/B, PTO-2054-A/B, PTO-2055-A/B, PTOL-413A.

Type of Review: Approved through September of 2007.

Affected Public: Individuals or households, business or other for-profit institutions, not-for-profit institutions, farms, Federal Government and State, Local and Tribal Governments.

Estimated Number of Respondents: 2,508,139.

Estimated Time Per Response: 1 minute and 48 seconds to 24 hours.

Estimated Total Annual Burden Hours: 3,724,791 hours.

Needs and Uses: During the processing of an application for a patent, the applicant or applicant's representative may be required or desire to submit additional information to the United States Patent and Trademark Office concerning the examination of a specific application. The specific information required or which may be submitted includes: information disclosure statement and citation, examination support documents, requests for extensions of time, the establishment of small entity status, abandonment and revival of abandoned applications, disclaimers, appeals, petitions, expedited examination of design applications, transmittal forms, requests to inspect, copy and access patent applications, publication requests, and certificates of mailing, transmittals, and submission of priority documents and amendments.

Comments are invited on: (1) Whether the collection of information is necessary for proper performance of the functions of the agency; (2) the accuracy of the agency's estimate of the burden; (3) ways to enhance the quality, utility, and clarity of the information to be

collected; and (4) ways to minimize the burden of the collection of information to respondents.

Interested persons are requested to send comments regarding these information collections, including suggestions for reducing this burden, to: (1) The Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10202, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Officer for the Patent and Trademark Office; and (2) Robert A. Clarke, Director, Office of Patent Legal Administration, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

List of Subjects in 37 CFR Part 1

Administrative practice and procedure, Courts, Freedom of Information, Inventions and patents, Reporting and recordkeeping requirements, Small Businesses.

- For the reasons set forth in the preamble, 37 CFR part 1 is amended as follows:

PART 1—RULES OF PRACTICE IN PATENT CASES

- 1. The authority citation for 37 CFR part 1 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2).

- 2. Section 1.17 is amended by revising paragraph (f) to read as follows:

§ 1.17 Patent application and reexamination processing fees.

* * * * *

(f) For filing a petition under one of the following sections which refers to this paragraph: \$400.00

§ 1.36(a)—for revocation of a power of attorney by fewer than all of the applicants.

§ 1.53(e)—to accord a filing date.

§ 1.57(a)—to accord a filing date.

§ 1.78(d)(1)(vi)—for a continuing application not provided for in §§ 1.78(d)(1)(i) through (d)(1)(v).

§ 1.114(g)—for a request for continued examination not provided for in § 1.114(f).

§ 1.182—for decision on a question not specifically provided for.

§ 1.183—to suspend the rules.

§ 1.378(e)—for reconsideration of decision on petition refusing to accept

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delayed payment of maintenance fee in an expired patent.

§ 1.741(b)—to accord a filing date to an application under § 1.740 for extension of a patent term.

* * * * *

■ 3. Section 1.26 is amended by revising paragraphs (a) and (b) to read as follows:

§ 1.26 Refunds.

(a) The Director may refund any fee paid by mistake or in excess of that required. Except as provided in § 1.117 or § 1.138(d), a change of purpose after the payment of a fee, such as when a party desires to withdraw a patent filing for which the fee was paid, including an application, an appeal, or a request for an oral hearing, will not entitle a party to a refund of such fee. The Office will not refund amounts of twenty-five dollars or less unless a refund is specifically requested, and will not notify the payor of such amounts. If a party paying a fee or requesting a refund does not provide the banking information necessary for making refunds by electronic funds transfer (31 U.S.C. 3332 and 31 CFR part 208), or instruct the Office that refunds are to be credited to deposit account, the Director may require such information, or use the banking information on the payment instrument to make a refund. Any refund of a fee paid by credit card will be by a credit to the credit card account to which the fee was charged.

(b) Any request for refund must be filed within two years from the date the fee was paid, except as otherwise provided in this paragraph, or in § 1.28(a), § 1.117(b), or § 1.138(d). If the Office charges a deposit account by an amount other than an amount specifically indicated in an authorization (§ 1.25(b)), any request for refund based upon such charge must be filed within two years from the date of the deposit account statement indicating such charge, and include a copy of that deposit account statement. The time periods set forth in this paragraph are not extendable.

* * * * *

■ 4. Section 1.52 is amended by revising paragraph (d)(2) to read as follows:

§ 1.52 Language, paper, writing, margins, compact disc specifications.

* * * * *

(d) * * *

(2) *Provisional application.* If a provisional application is filed in a language other than English and the benefit of such provisional application is claimed in a nonprovisional application, an English language translation of the non-English language

provisional application will be required in the provisional application. See § 1.78(b).

* * * * *

■ 5. Section 1.53 is amended by revising paragraphs (b) and (c)(4) to read as follows:

§ 1.53 Application number, filing date, and completion of application.

* * * * *

(b) *Application filing requirements—Nonprovisional application.* The filing date of an application for patent filed under this section, except for a provisional application under paragraph (c) of this section or a continued prosecution application under paragraph (d) of this section, is the date on which a specification as prescribed by 35 U.S.C. 112 containing a description pursuant to § 1.71 and at least one claim pursuant to § 1.75, and any drawing required by § 1.81(a) are filed in the Patent and Trademark Office. No new matter may be introduced into an application after its filing date. A continuing application, which may be a continuation, divisional, or continuation-in-part application, may be filed under this section if the conditions specified in 35 U.S.C. 120, 121, or 365(c) and § 1.78 are met.

(1) A continuation or divisional application that names as inventors the same or fewer than all of the inventors named in the prior application may be filed under paragraph (b) or (d) of this section. A continuation or divisional application naming an inventor not named in the prior application must be filed under paragraph (b) of this section. See § 1.78(a)(2) for the definition of a divisional application and § 1.78(a)(3) for the definition of a continuation application.

(2) A continuation-in-part application must be filed under paragraph (b) of this section. See § 1.78(a)(4) for the definition of a continuation-in-part application.

(c) * * *

(4) A provisional application is not entitled to the right of priority under 35 U.S.C. 119 or 365(a) or § 1.55, or to the benefit of an earlier filing date under 35 U.S.C. 120, 121 or 365(c) or § 1.78 of any other application. No claim for priority under 35 U.S.C. 119(e) or § 1.78 may be made in a design application based on a provisional application. No request under § 1.293 for a statutory invention registration may be filed in a provisional application. The requirements of §§ 1.821 through 1.825 regarding application disclosures containing nucleotide and/or amino acid sequences

are not mandatory for provisional applications.

* * * * *

■ 6. Section 1.75 is amended by revising paragraphs (b) and (c) to read as follows:

§ 1.75 Claim(s).

* * * * *

(b) More than one claim may be presented provided they differ substantially from each other and are not unduly multiplied. One or more claims may be presented in dependent form, referring back to and further limiting another claim or claims in the same application. A dependent claim must contain a reference to a claim previously set forth in the same application, incorporate by reference all the limitations of the previous claim to which such dependent claim refers, and specify a further limitation of the subject matter of the previous claim.

(1) An applicant must file an examination support document in compliance with § 1.265 that covers each claim (whether in independent or dependent form) before the issuance of a first Office action on the merits of the application if the application contains or is amended to contain more than five independent claims or more than twenty-five total claims. An application may not contain or be amended to contain more than five independent claims or more than twenty-five total claims if an examination support document in compliance with § 1.265 has not been filed before the issuance of a first Office action on the merits of the application.

(2) A claim that refers to another claim but does not incorporate by reference all of the limitations of the claim to which such claim refers will be treated as an independent claim for fee calculation purposes under § 1.16 (or § 1.492) and for purposes of paragraph (b) of this section. A claim that refers to a claim of a different statutory class of invention will also be treated as an independent claim for fee calculation purposes under § 1.16 (or § 1.492) and for purposes of paragraph (b) of this section.

(3) The applicant will be notified if the application contains or is amended to contain more than five independent claims or more than twenty-five total claims but the applicant has not complied with the requirements set forth in paragraph (b)(1) or (b)(4) of this section. If the non-compliance appears to have been inadvertent, the notice will set a two-month time period that is not extendable under § 1.136(a) within which, to avoid abandonment of the application, the applicant must comply

with the requirements set forth in paragraph (b) of this section.

(4) If a nonprovisional application contains at least one claim that is patentably indistinct from at least one claim in one or more other pending nonprovisional applications, and if such one or more other nonprovisional applications and the first nonprovisional application are owned by the same person, or are subject to an obligation of assignment to the same person, the Office will treat the claims (whether in independent or dependent form) in the first nonprovisional application and in each of such other pending nonprovisional applications as present in each of the nonprovisional applications for purposes of paragraph (b) of this section.

(5) Claims withdrawn from consideration under §§ 1.141 through 1.146 or § 1.499 as drawn to a non-elected invention or inventions will not, unless they are reinstated or rejoined, be taken into account in determining whether an application exceeds the five independent claim and twenty-five total claim threshold set forth in paragraphs (b)(1), (b)(3), and (b)(4) of this section.

(c) Any dependent claim which refers to more than one other claim ("multiple dependent claim") shall refer to such other claims in the alternative only. A multiple dependent claim shall not serve as a basis for any other multiple dependent claim. For fee calculation purposes under § 1.16 (or § 1.492) and for purposes of paragraph (b) of this section, a multiple dependent claim will be considered to be that number of claims to which direct reference is made therein. For fee calculation purposes under § 1.16 (or § 1.492) and for purposes of paragraph (b) of this section, any claim depending from a multiple dependent claim will be considered to be that number of claims to which direct reference is made in that multiple dependent claim. In addition to the other filing fees, any application which is filed with, or is amended to include, multiple dependent claims must have paid therein the fee set forth in § 1.16(j). A multiple dependent claim shall be construed to incorporate by reference all the limitations of each of the particular claims in relation to which it is being considered.

* * * * *

■ 7. Section 1.76 is amended by revising paragraph (b)(5) to read as follows:

§ 1.76 Application data sheet.

* * * * *

(b) * * *

(5) Domestic priority information.

This information includes the application number, the filing date, and

relationship of each application for which a benefit is claimed under 35 U.S.C. 120, 121, or 365(c). This information includes the application number and the filing date of each application for which a benefit is claimed under 35 U.S.C. 119(e). Providing this information in the application data sheet also constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and § 1.78(b)(3) or § 1.78(d)(3), and need not otherwise be made part of the specification.

* * * * *

■ 8. Section 1.78 is revised to read as follows:

§ 1.78 Claiming benefit of earlier filing date and cross-references to other applications.

(a) *Definitions*—(1) *Continuing application*. A continuing application is a nonprovisional application or an international application designating the United States of America that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of a prior-filed nonprovisional application or international application designating the United States of America. An application that does not claim the benefit under 35 U.S.C. 120, 121, or 365(c) of a prior-filed application is not a continuing application even if the application claims the benefit under 35 U.S.C. 119(e) of a provisional application, claims priority under 35 U.S.C. 119(a)-(d) or 365(b) to a foreign application, or claims priority under 35 U.S.C. 365(a) or (b) to an international application designating at least one country other than the United States of America.

(2) *Divisional application*. A divisional application is a continuing application as defined in paragraph (a)(1) of this section that discloses and claims only an invention or inventions that were disclosed and claimed in a prior-filed application, but were subject to a requirement to comply with the requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121 in the prior-filed application, and were not elected for examination and were not examined in any prior-filed application.

(3) *Continuation application*. A continuation application is a continuing application as defined in paragraph (a)(1) of this section that discloses and claims only an invention or inventions that were disclosed in the prior-filed application.

(4) *Continuation-in-part application*. A continuation-in-part application is a continuing application as defined in paragraph (a)(1) of this section that discloses subject matter that was not disclosed in the prior-filed application.

(b) *Claims under 35 U.S.C. 119(e) for the benefit of a prior-filed provisional application*. A nonprovisional application, other than for a design patent, or an international application designating the United States of America may claim the benefit of one or more prior-filed provisional applications under the conditions set forth in 35 U.S.C. 119(e) and paragraph (b) of this section.

(1) The nonprovisional application or international application designating the United States of America must be filed not later than twelve months after the date on which the provisional application was filed. This twelve-month period is subject to 35 U.S.C. 21(b) and § 1.7(a).

(2) Each prior-filed provisional application must name as an inventor at least one inventor named in the later-filed application. In addition, each prior-filed provisional application must be entitled to a filing date as set forth in § 1.53(c) and the basic filing fee set forth in § 1.16(d) must have been paid for such provisional application within the time period set forth in § 1.53(g).

(3) Any nonprovisional application or international application designating the United States of America that claims the benefit of one or more prior-filed provisional applications must contain or be amended to contain a reference to each such prior-filed provisional application, identifying it by the provisional application number (consisting of series code and serial number). If the later-filed application is a nonprovisional application, the reference required by this paragraph must be included in an application data sheet (§ 1.76), or the specification must contain or be amended to contain such reference in the first sentence(s) following the title.

(4) The reference required by paragraph (b)(3) of this section must be submitted during the pendency of the later-filed application. If the later-filed application is an application filed under 35 U.S.C. 111(a), this reference must also be submitted within the later of four months from the actual filing date of the later-filed application or sixteen months from the filing date of the prior-filed provisional application. If the later-filed application is a nonprovisional application which entered the national stage from an international application after compliance with 35 U.S.C. 371, this reference must also be submitted within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) in the later-filed international application or sixteen months from the filing date of the prior-

filed provisional application. Except as provided in paragraph (c) of this section, failure to timely submit the reference is considered a waiver of any benefit under 35 U.S.C. 119(e) of the prior-filed provisional application. The time periods in this paragraph do not apply if the later-filed application is:

(i) An application filed under 35 U.S.C. 111(a) before November 29, 2000; or

(ii) An international application filed under 35 U.S.C. 363 before November 29, 2000.

(5) If the prior-filed provisional application was filed in a language other than English and both an English-language translation of the prior-filed provisional application and a statement that the translation is accurate were not previously filed in the prior-filed provisional application, applicant will be notified and given a period of time within which to file the translation and the statement in the prior-filed provisional application. If the notice is mailed in a pending nonprovisional application, a timely reply to such a notice must include the filing in the nonprovisional application of either a confirmation that the translation and statement were filed in the provisional application, or an amendment or supplemental application data sheet withdrawing the benefit claim, or the nonprovisional application will be abandoned. The translation and statement may be filed in the provisional application, even if the provisional application has become abandoned.

(c) *Delayed claims under 35 U.S.C. 119(e) for the benefit of a prior-filed provisional application.* If the reference required by 35 U.S.C. 119(e) and paragraph (b)(3) of this section is presented in a nonprovisional application after the time period provided by paragraph (b)(4) of this section, the claim under 35 U.S.C. 119(e) for the benefit of a prior-filed provisional application may be accepted if submitted during the pendency of the later-filed application and if the reference identifying the prior-filed application by provisional application number was unintentionally delayed. A petition to accept an unintentionally delayed claim under 35 U.S.C. 119(e) for the benefit of a prior-filed provisional application must be accompanied by:

(1) The reference required by 35 U.S.C. 119(e) and paragraph (b)(3) of this section to the prior-filed provisional application, unless previously submitted;

(2) The surcharge set forth in § 1.17(t); and

(3) A statement that the entire delay between the date the claim was due under paragraph (b)(4) of this section and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional.

(d) *Claims under 35 U.S.C. 120, 121, or 365(c) for the benefit of a prior-filed nonprovisional or international application.* A nonprovisional application (including an international application that has entered the national stage after compliance with 35 U.S.C. 371) may claim the benefit of one or more prior-filed copending nonprovisional applications or international applications designating the United States of America under the conditions set forth in 35 U.S.C. 120 and paragraph (d) of this section.

(1) A nonprovisional application that claims the benefit of one or more prior-filed copending nonprovisional applications or international applications designating the United States of America must satisfy the conditions set forth in at least one of paragraphs (d)(1)(i) through (d)(1)(vi) of this section. The Office will refuse to enter, or will delete if present, any specific reference to a prior-filed application that is not permitted by at least one of paragraphs (d)(1)(i) through (d)(1)(vi) of this section. The Office's entry of, or failure to delete, a specific reference to a prior-filed application that is not permitted by at least one of paragraphs (d)(1)(i) through (d)(1)(vi) of this section does not constitute a waiver of the provisions of paragraph (d)(1) of this section.

(i)(A) The nonprovisional application is either a continuation application as defined in paragraph (a)(3) of this section or a continuation-in-part application as defined in paragraph (a)(4) of this section that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of no more than two prior-filed applications; and

(B) Any application whose benefit is claimed under 35 U.S.C. 120, 121, or 365(c) in such nonprovisional application has its benefit claimed in no more than one other nonprovisional application, not including any nonprovisional application that satisfies the conditions set forth in paragraph (d)(1)(ii), (d)(1)(iii) or (d)(1)(vi) of this section.

(ii)(A) The nonprovisional application is a divisional application as defined in paragraph (a)(2) of this section that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of a prior-filed application that was subject to a requirement to comply with the

requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121; and

(B) The divisional application contains only claims directed to an invention or inventions that were identified in such requirement to comply with the requirement of unity of invention or requirement for restriction but were not elected for examination and were not examined in the prior-filed application or in any other nonprovisional application, except for a nonprovisional application that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of such divisional application and satisfies the conditions set forth in paragraph (d)(1)(iii) or (d)(1)(vi) of this section.

(iii)(A) The nonprovisional application is a continuation application as defined in paragraph (a)(3) of this section that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of a divisional application that satisfies the conditions set forth in paragraph (d)(1)(ii) of this section;

(B) The nonprovisional application discloses and claims only an invention or inventions that were disclosed and claimed in such divisional application;

(C) The nonprovisional application claims the benefit under 35 U.S.C. 120, 121, or 365(c) of only the divisional application, any application to which such divisional application claims benefit under 35 U.S.C. 120, 121, or 365(c) in compliance with the conditions set forth in paragraph (d)(1)(ii) of this section, and no more than one intervening prior-filed nonprovisional application; and

(D) The divisional application whose benefit is claimed under 35 U.S.C. 120, 121, or 365(c) in such nonprovisional application has its benefit claimed in no more than one other nonprovisional application, not including any other divisional application that satisfies the conditions set forth in paragraph (d)(1)(ii) or any nonprovisional application that claims the benefit under 35 U.S.C. 120 or 365(c) of such other divisional application and satisfies the conditions set forth in paragraph (d)(1)(iii) or (d)(1)(vi) of this section.

(iv)(A) The nonprovisional application claims benefit under 35 U.S.C. 120 or 365(c) of a prior-filed international application designating the United States of America, and a Demand has not been filed and the basic national fee (§ 1.492(a)) has not been paid in the prior-filed international application and the prior-filed international application does not claim the benefit of any other nonprovisional application or international application

designating the United States of America;

(B) The nonprovisional application is either a continuation application as defined in paragraph (a)(3) of this section or a continuation-in-part application as defined in paragraph (a)(4) of this section that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of no more than three prior-filed applications; and

(C) Any application whose benefit is claimed under 35 U.S.C. 120, 121, or 365(c) in such nonprovisional application has its benefit claimed in no more than two other nonprovisional applications, not including any nonprovisional application that satisfies the conditions set forth in paragraph (d)(1)(ii), (d)(1)(iii) or (d)(1)(vi) of this section.

(v)(A) The nonprovisional application claims benefit under 35 U.S.C. 120 or 365(c) of a prior-filed nonprovisional application filed under 35 U.S.C. 111(a), and such nonprovisional application became abandoned due to the failure to timely reply to an Office notice issued under § 1.53(f) and does not claim the benefit of any other nonprovisional application or international application designating the United States of America;

(B) The nonprovisional application is either a continuation application as defined in paragraph (a)(3) of this section or a continuation-in-part application as defined in paragraph (a)(4) of this section that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of no more than three prior-filed applications; and

(C) Any application whose benefit is claimed under 35 U.S.C. 120, 121, or 365(c) in such nonprovisional application has its benefit claimed in no more than two other nonprovisional applications, not including any nonprovisional application that satisfies the conditions set forth in paragraph (d)(1)(ii), (d)(1)(iii) or (d)(1)(vi) of this section.

(vi) The nonprovisional application is a continuing application as defined in paragraph (a)(1) of this section that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of a prior-filed application, is filed to obtain consideration of an amendment, argument, or evidence that could not have been submitted during the prosecution of the prior-filed application, and does not satisfy the conditions set forth in any of paragraphs (d)(1)(i) through (d)(1)(v) of this section. A petition must be filed in such nonprovisional application that is accompanied by the fee set forth in § 1.17(f) and a showing that the

amendment, argument, or evidence sought to be entered could not have been submitted during the prosecution of the prior-filed application. If the continuing application is an application filed under 35 U.S.C. 111(a), this petition must be submitted within four months from the actual filing date of the continuing application. If the continuing application is a nonprovisional application which entered the national stage from an international application after compliance with 35 U.S.C. 371, this petition must be submitted within four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) in the international application.

(2) Each prior-filed application must name as an inventor at least one inventor named in the later-filed application. In addition, each prior-filed application must either be:

(i) An international application entitled to a filing date in accordance with PCT Article 11 and designating the United States of America; or

(ii) A nonprovisional application under 35 U.S.C. 111(a) that is entitled to a filing date as set forth in § 1.53(b) or § 1.53(d) for which the basic filing fee set forth in § 1.16 has been paid within the pendency of the application.

(3) Except for a continued prosecution application filed under § 1.53(d), any nonprovisional application, or international application designating the United States of America, that claims the benefit of one or more prior-filed nonprovisional applications or international applications designating the United States of America must contain or be amended to contain a reference to each such prior-filed application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date. The reference must also identify the relationship of the applications (*i.e.*, whether the later-filed application is a continuation, divisional, or continuation-in-part of the prior-filed nonprovisional application or international application). If an application is identified as a continuation-in-part application, the applicant must identify the claim or claims in the continuation-in-part application for which the subject matter is disclosed in the manner provided by the first paragraph of 35 U.S.C. 112 in the prior-filed application. If the later-filed application is a nonprovisional application, the reference required by this paragraph must be included in an application data sheet (§ 1.76), or the specification must contain or be

amended to contain such reference in the first sentence(s) following the title.

(4) The reference required by 35 U.S.C. 120 and paragraph (d)(3) of this section must be submitted during the pendency of the later-filed application. If the later-filed application is an application filed under 35 U.S.C. 111(a), this reference must also be submitted within the later of four months from the actual filing date of the later-filed application or sixteen months from the filing date of the prior-filed application. If the later-filed application is a nonprovisional application which entered the national stage from an international application after compliance with 35 U.S.C. 371, this reference must also be submitted within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) in the later-filed international application or sixteen months from the filing date of the prior-filed application. Except as provided in paragraph (e) of this section, failure to timely submit the reference required by 35 U.S.C. 120 and paragraph (d)(3) of this section is considered a waiver of any benefit under 35 U.S.C. 120, 121, or 365(c) to the prior-filed application. The time periods in this paragraph do not apply if the later-filed application is:

(i) An application for a design patent;
(ii) An application filed under 35 U.S.C. 111(a) before November 29, 2000; or

(iii) An international application filed under 35 U.S.C. 363 before November 29, 2000.

(5) The request for a continued prosecution application under § 1.53(d) is the specific reference required by 35 U.S.C. 120 to the prior-filed application. The identification of an application by application number under this section is the identification of every application assigned that application number necessary for a specific reference required by 35 U.S.C. 120 to every such application assigned that application number.

(6) Cross-references to other related applications may be made when appropriate. Cross-references to applications for which a benefit is not claimed under title 35, United States Code, must be located in a paragraph that is separate from the paragraph containing the references to applications for which a benefit is claimed under 35 U.S.C. 119(e), 120, 121, or 365(c) that is required by 35 U.S.C. 119(e) or 120 and this section.

(e) *Delayed claims under 35 U.S.C. 120, 121, or 365(c) for the benefit of a prior-filed nonprovisional application or international application.* If the reference required by 35 U.S.C. 120 and

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paragraph (d)(3) of this section is presented after the time period provided by paragraph (d)(4) of this section, the claim under 35 U.S.C. 120, 121, or 365(c) for the benefit of a prior-filed copending nonprovisional application or international application designating the United States of America may be accepted if the reference identifying the prior-filed application by application number or international application number and international filing date was unintentionally delayed. A petition to accept an unintentionally delayed claim under 35 U.S.C. 120, 121, or 365(c) for the benefit of a prior-filed application must be accompanied by:

(1) The reference required by 35 U.S.C. 120 and paragraph (d)(3) of this section to the prior-filed application, unless previously submitted;

(2) The surcharge set forth in § 1.17(t); and

(3) A statement that the entire delay between the date the claim was due under paragraph (d)(4) of this section and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional.

(f) *Applications and patents naming at least one inventor in common.* (1)(i) The applicant in a nonprovisional application that has not been allowed (§ 1.311) must identify by application number (*i.e.*, series code and serial number) and patent number (if applicable) each other pending or patented nonprovisional application, in a separate paper, for which the following conditions are met:

(A) The nonprovisional application has a filing date that is the same as or within two months of the filing date of the other pending or patented nonprovisional application, taking into account any filing date for which a benefit is sought under title 35, United States Code;

(B) The nonprovisional application names at least one inventor in common with the other pending or patented nonprovisional application; and

(C) The nonprovisional application is owned by the same person, or subject to an obligation of assignment to the same person, as the other pending or patented nonprovisional application.

(ii) The identification of such one or more other pending or patented nonprovisional applications if required by paragraph (f)(1)(i) of this section must be submitted within the later of:

(A) Four months from the actual filing date in a nonprovisional application filed under 35 U.S.C. 111(a);

(B) Four months from the date on which the national stage commenced

under 35 U.S.C. 371(b) or (f) in a nonprovisional application entering the national stage from an international application under 35 U.S.C. 371; or

(C) Two months from the mailing date of the initial filing receipt in such other nonprovisional application for which identification is required by paragraph (f)(1)(i) of this section.

(2)(i) A rebuttable presumption shall exist that a nonprovisional application contains at least one claim that is not patentably distinct from at least one of the claims in another pending or patented nonprovisional application if the following conditions are met:

(A) The nonprovisional application has a filing date that is the same as the filing date of the other pending or patented nonprovisional application, taking into account any filing date for which a benefit is sought under title 35, United States Code;

(B) The nonprovisional application names at least one inventor in common with the other pending or patented nonprovisional application;

(C) The nonprovisional application is owned by the same person, or subject to an obligation of assignment to the same person, as the other pending or patented nonprovisional application; and

(D) The nonprovisional application and the other pending or patented nonprovisional application contain substantial overlapping disclosure. Substantial overlapping disclosure exists if the other pending or patented nonprovisional application has written description support under the first paragraph of 35 U.S.C. 112 for at least one claim in the nonprovisional application.

(ii) If the conditions specified in paragraph (f)(2)(i) of this section exist, the applicant in the nonprovisional application must, unless the nonprovisional application has been allowed (§ 1.311), take one of the following actions within the time period specified in paragraph (f)(2)(iii) of this section:

(A) Rebut this presumption by explaining how the application contains only claims that are patentably distinct from the claims in each of such other pending nonprovisional applications or patents; or

(B) Submit a terminal disclaimer in accordance with § 1.321(c). In addition, where one or more other pending nonprovisional applications have been identified, the applicant must explain why there are two or more pending nonprovisional applications naming at least one inventor in common and owned by the same person, or subject to an obligation of assignment to the same

person, which contain patentably indistinct claims.

(iii) If the conditions specified in paragraph (f)(2)(i) of this section exist, the applicant in the nonprovisional application must, unless the nonprovisional application has been allowed (§ 1.311), take one of the actions specified in paragraph (f)(2)(ii) of this section within the later of:

(A) Four months from the actual filing date of a nonprovisional application filed under 35 U.S.C. 111(a);

(B) Four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) in a nonprovisional application entering the national stage from an international application under 35 U.S.C. 371;

(C) The date on which a claim that is not patentably distinct from at least one of the claims in the one or more other pending or patented nonprovisional applications is presented; or

(D) Two months from the mailing date of the initial filing receipt in the one or more other pending or patented nonprovisional applications.

(3) In the absence of good and sufficient reason for there being two or more pending nonprovisional applications owned by the same person, or subject to an obligation of assignment to the same person, which contain patentably indistinct claims, the Office may require elimination of the patentably indistinct claims from all but one of the applications.

(g) *Applications or patents under reexamination naming different inventors and containing patentably indistinct claims.* If an application or a patent under reexamination and at least one other application naming different inventors are owned by the same party and contain patentably indistinct claims, and there is no statement of record indicating that the claimed inventions were commonly owned or subject to an obligation of assignment to the same person at the time the later invention was made, the Office may require the assignee to state whether the claimed inventions were commonly owned or subject to an obligation of assignment to the same person at the time the later invention was made, and if not, indicate which named inventor is the prior inventor.

(h) *Parties to a joint research agreement.* If an application discloses or is amended to disclose the names of parties to a joint research agreement under 35 U.S.C. 103(c)(2)(C), the parties to the joint research agreement are considered to be the same person for purposes of this section. If the application is amended to disclose the names of parties to a joint research

agreement, the identification of such one or more other nonprovisional applications as required by paragraph (f)(1) of this section must be submitted with such amendment unless such identification is or has been submitted within the four-month period specified in paragraph (f)(1) of this section.

(i) *Time periods not extendable:* The time periods set forth in this section are not extendable.

■ 9. Section 1.104 is amended by revising paragraphs (a)(1) and (b) to read as follows:

§ 1.104 Nature of examination.

(a) *Examiner's action.* (1) On taking up an application for examination or a patent in a reexamination proceeding, the examiner shall make a thorough study thereof and shall make a thorough investigation of the available prior art relating to the subject matter of the claimed invention. The examination shall be complete with respect both to compliance of the application or patent under reexamination with the applicable statutes, rules, and other requirements, and to the patentability of the invention as claimed, as well as with respect to matters of form, unless otherwise indicated.

* * * *

(b) *Completeness of examiner's action.* The examiner's action will be complete as to all matters, except that in appropriate circumstances, such as misjoinder of invention, fundamental defects in the application, and the like, the action of the examiner may be limited to such matters before further action is made.

* * * *

■ 10. Section 1.105 is amended by adding a new paragraph (a)(1)(ix) to read as follows:

§ 1.105 Requirements for information.

(a)(1) * * *

(ix) *Support in the specification:* Where (by page and line or paragraph number) in the specification of the application, or any application the benefit of whose filing date is sought under title 35, United States Code, there is written description support for the invention as defined in the claims (whether in independent or dependent form), and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention, under the first paragraph of 35 U.S.C. 112.

* * * *

■ 11. Section 1.110 is revised to read as follows:

§ 1.110 Inventorship and date of invention of the subject matter of individual claims.

When more than one inventor is named in an application or patent, the Office may require an applicant, patentee, or owner to identify the inventive entity of the subject matter of each claim in the application or patent when necessary for purposes of an Office proceeding. Where appropriate, the invention dates of the subject matter of each claim and the ownership of the subject matter on the date of invention may be required of the applicant, patentee or owner. See also §§ 1.78 and 1.130.

■ 12. Section 1.114 is amended by revising paragraphs (a) and (d), and by adding new paragraphs (f), (g), and (h), to read as follows:

§ 1.114 Request for continued examination.

(a) If prosecution in an application is closed, an applicant may, subject to the conditions of this section, file a request for continued examination of the application accompanied by a submission, the fee set forth in § 1.17(e), and if required, a petition under paragraph (g) of this section accompanied by the fee set forth in § 1.17(f), prior to the earliest of:

(1) Payment of the issue fee, unless a petition under § 1.313 is granted;

(2) Abandonment of the application; or

(3) The filing of a notice of appeal to the U.S. Court of Appeals for the Federal Circuit under 35 U.S.C. 141, or the commencement of a civil action under 35 U.S.C. 145 or 146, unless the appeal or civil action is terminated.

* * * *

(d) If an applicant files a request for continued examination under this section after appeal, but prior to a decision on the appeal, the request for continued examination will also be treated as a request to withdraw the appeal and to reopen prosecution of the application before the examiner. An appeal brief (§ 41.37 of this title), a reply brief (§ 41.41 of this title), or related papers will not be considered a submission under this section.

* * * *

(f) An applicant may file a request for continued examination under this section in an application without a petition under paragraph (g) of this section if the conditions set forth in at least one of paragraphs (f)(1), (f)(2), or (f)(3) of this section are satisfied:

(1) A request for continued examination under this section has not previously been filed in any of:

(i) The application;

(ii) Any application whose benefit is claimed under 35 U.S.C. 120, 121, or 365(c) in such application; and

(iii) Any application that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of such application, not including any nonprovisional application that satisfies the conditions set forth in § 1.78(d)(1)(ii), (d)(1)(iii) or (d)(1)(vi).

(2) The application is a divisional application that satisfies the conditions set forth in § 1.78(d)(1)(ii), and a request for continued examination under this section has not previously been filed in any of:

(i) The divisional application; and

(ii) Any application that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of such divisional application, not including any nonprovisional application that satisfies the conditions set forth in § 1.78(d)(1)(ii), (d)(1)(iii) or (d)(1)(vi).

(3) The application is a continuation application that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of a divisional application and satisfies the conditions set forth in § 1.78(d)(1)(iii), and a request for continued examination under this section has not been filed in any of:

(i) The continuation application;

(ii) The divisional application; and

(iii) Any other application that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of such divisional application, not including any nonprovisional application that satisfies the conditions set forth in § 1.78(d)(1)(ii), (d)(1)(iii) or (d)(1)(vi).

(g) A request for continued examination must include a petition accompanied by the fee set forth in § 1.17(f) and a showing that the amendment, argument, or evidence sought to be entered could not have been submitted prior to the close of prosecution in the application, except as otherwise provided in paragraph (f) of this section.

(h) The filing of an improper request for continued examination, including a request for continued examination with a petition under paragraph (g) of this section that is not grantable, will not stay any period for reply that may be running against the application, nor act as a stay of other proceedings.

■ 13. Section 1.117 is added to read as follows:

§ 1.117 Refund due to cancellation of claim.

(a) If an amendment canceling a claim is filed before an examination on the merits has been made of the application, the applicant may request a refund of any fee under § 1.16(h), (i), or (j) or under § 1.492(d), (e), or (f) paid on or after December 8, 2004, for such claim. If an amendment adding one or more claims is also filed before the application has been taken up for examination on the merits, the Office may apply any refund under § 1.117 to any excess claims fees due as a result of such an amendment. The date indicated on any certificate of mailing or transmission under § 1.8 will not be taken into account in determining whether an amendment canceling a claim was filed before an examination on the merits has been made of the application.

(b) If a request for refund under this section is not filed within two months from the date on which the claim was canceled, the Office may retain the excess claims fee paid in the application. This two-month period is not extendable. If an amendment canceling a claim is not filed before an examination on the merits has been made of the application, the Office will not refund any part of the excess claims fee paid in the application except as provided in § 1.26.

■ 14. Section 1.136 is amended by revising paragraph (a)(1) to read as follows:

§ 1.136 Extensions of time.

(a)(1) If an applicant is required to reply within a nonstatutory or shortened statutory time period, applicant may extend the time period for reply up to the earlier of the expiration of any maximum period set by statute or five months after the time period set for reply, if a petition for an extension of time and the fee set in § 1.17(a) are filed, unless:

- (i) Applicant is notified otherwise in an Office action;
- (ii) The reply is to a notice requiring compliance with § 1.75(b) or § 1.265;
- (iii) The reply is a reply brief submitted pursuant to § 41.41 of this title;

- (iv) The reply is a request for an oral hearing submitted pursuant to § 41.47(a) of this title;

- (v) The reply is to a decision by the Board of Patent Appeals and Interferences pursuant to § 1.304 or to § 41.50 or § 41.52 of this title; or

- (vi) The application is involved in a contested case (§ 41.101(a) of this title).

* * * * *

■ 15. Section 1.142 is amended by revising paragraph (a) and adding new paragraph (c) to read as follows:

§ 1.142 Requirement for restriction.

(a) If two or more independent and distinct inventions are claimed in a single application, the examiner in an Office action may require the applicant in the reply to that action to elect an invention to which the claims will be restricted, this official action being called a requirement for restriction (also known as a requirement for division). Such requirement will normally be made before any action on the merits; however, it may be made at any time before final action.

(c) If two or more independent and distinct inventions are claimed in a single application, the applicant may file a suggested requirement for restriction under this paragraph. Any suggested requirement for restriction must be filed prior to the earlier of the first Office action on the merits or an Office action that contains a requirement to comply with the requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121 in the application. Any suggested requirement for restriction must also be accompanied by an election without traverse of an invention to which there are no more than five independent claims and no more than twenty-five total claims, and must identify the claims to the elected invention. If the suggested requirement for restriction is accepted, the applicant will be notified in an Office action that will contain a requirement for restriction under paragraph (a) of this section. Any claim to the non-elected invention or inventions, if not canceled, is by the election withdrawn from further consideration.

■ 16. Section 1.145 is revised to read as follows:

§ 1.145 Subsequent presentation of claims for different invention.

If, after an Office action on the merits on an application, the applicant presents claims directed to an invention distinct from and independent of the invention previously claimed, the applicant may be required to restrict the claims to the invention previously claimed if the amendment is entered, subject to reconsideration and review as provided in §§ 1.143 and 1.144.

■ 17. Section 1.265 is added to read as follows:

§ 1.265 Examination support document.

(a) An examination support document as used in this part means a document that includes the following:

- (1) A statement that a preexamination search in compliance with paragraph (b) of this section was conducted, including an identification of the field of search by United States class and subclass and the date of the search, where applicable, and, for database searches, the search logic or chemical structure or sequence used as a query, the name of the file or files searched and the database service, and the date of the search;

- (2) A listing of the reference or references deemed most closely related to the subject matter of each of the claims (whether in independent or dependent form) in compliance with paragraph (c) of this section;

- (3) For each reference cited, an identification of all of the limitations of each of the claims (whether in independent or dependent form) that are disclosed by the reference;

- (4) A detailed explanation particularly pointing out how each of the independent claims is patentable over the cited references; and

- (5) A showing of where each limitation of each of the claims (whether in independent or dependent form) finds support under the first paragraph of 35 U.S.C. 112 in the written description of the specification. If the application claims the benefit of one or more applications under title 35, United States Code, the showing must also include where each limitation of each of the claims finds support under the first paragraph of 35 U.S.C. 112 in each such priority or benefit application in which such support exists.

- (b) The preexamination search referred to in paragraph (a)(1) of this section must involve U.S. patents and patent application publications, foreign patent documents, and non-patent literature, unless the applicant justifies with reasonable certainty that no references more pertinent than those already identified are likely to be found in the eliminated source and includes such a justification with the statement required by paragraph (a)(1) of this section. The preexamination search referred to in paragraph (a)(1) of this section must be directed to the claimed invention and encompass all of the limitations of each of the claims (whether in independent or dependent form), giving the claims the broadest reasonable interpretation.

- (c) The listing of references required under paragraph (a)(2) of this section as part of an examination support document must include a list identifying each of the cited references

in compliance with paragraphs (c)(1) and (c)(2) of this section, a copy of each reference if required by paragraph (c)(3) of this section, and each English language translation if required by paragraph (c)(4) of this section.

(1) The list of cited references must itemize U.S. patents and U.S. patent application publications (including international applications designating the U.S.) in a section separate from the list of other references. Each page of the list of the cited references must include:

(i) The application number, if known, of the application in which the examination support document is being filed;

(ii) A column that provides a space next to each cited reference for the examiner's initials; and

(iii) A heading that clearly indicates that the list is part of an examination support document listing of references.

(2) The list of cited references must identify each cited reference as follows:

(i) Each U.S. patent must be identified by first named patentee, patent number, and issue date.

(ii) Each U.S. patent application publication must be identified by applicant, patent application publication number, and publication date.

(iii) Each U.S. application must be identified by the applicant, application number, and filing date.

(iv) Each foreign patent or published foreign patent application must be identified by the country or patent office which issued the patent or published the application, an appropriate document number, and the publication date indicated on the patent or published application.

(v) Each publication must be identified by publisher (e.g., name of journal), author (if any), title, relevant pages of the publication, date, and place of publication.

(3) The listing of references required under paragraph (a)(2) of this section must also be accompanied by a legible copy of each cited reference, except for references that are U.S. patents or U.S. patent application publications.

(4) If a non-English language document is being cited in the listing of references required under paragraph (a)(2) of this section as part of an examination support document, any existing English language translation of the non-English language document must also be submitted if the translation is within the possession, custody, or control of, or is readily available to any individual identified in § 1.56(c).

(d) If an information disclosure statement is filed in an application in

which an examination support document is required and has been filed, the applicant must also file a supplemental examination support document addressing the reference or references in the manner required under paragraphs (a)(3) and (a)(4) of this section unless the information disclosure statement cites only references that are less closely related to the subject matter of one or more claims (whether in independent or dependent form) than the references cited in the examination support document listing of references under paragraph (a)(2) of this section.

(e) If an examination support document is required, but the examination support document or preexamination search is deemed to be insufficient, or the claims have been amended such that the examination support document no longer covers each of the claims, applicant will be notified and given a two-month time period that is not extendable under § 1.136(a) within which, to avoid abandonment of the application, the applicant must:

(1) File a corrected or supplemental examination support document in compliance with this section that covers each of the claims (whether in independent or dependent form); or

(2) Amend the application such that it contains no more than five independent claims and no more than twenty-five total claims.

(f) An examination support document, or a corrected or supplemental examination support document, is not required to comply with the requirements set forth in paragraph (a)(3) of this section if the examination support document is accompanied by a certification that any rights in the application have not been assigned, granted, conveyed, or licensed, and there is no obligation under contract or law to assign, grant, convey, or license any rights in the application, other than a security interest that has not been defaulted upon, to any entity other than:

(1) A business or other concern;

(i) Whose number of employees, including affiliates, does not exceed 500 persons; and

(ii) Which has not assigned, granted, conveyed, or licensed (and is under no obligation to do so) any rights in the invention to any person who made it and could not be classified as an independent inventor, or to any concern which would not qualify as a non-profit organization or a small business concern under paragraph (f)(1)(i) of this section.

(2) A not-for-profit enterprise which is independently owned and operated and is not dominant in its field; or

(3) A government of a city, county, town, township, village, school district, or special district, with a population of less than fifty thousand.

■ 18. Section 1.495 is amended by revising paragraph (g) to read as follows:

§ 1.495 Entering the national stage in the United States of America.

* * * * *

(g) The documents and fees submitted under paragraphs (b) and (c) of this section must be clearly identified as a submission to enter the national stage under 35 U.S.C. 371. If the documents and fees contain conflicting indications as between an application under 35 U.S.C. 111 and a submission to enter the national stage under 35 U.S.C. 371, the documents and fees will be treated as a submission to enter the national stage under 35 U.S.C. 371.

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■ 19. Section 1.704 is amended by redesignating paragraph (c)(11) as (c)(12) and adding new paragraph (c)(11) to read as follows:

§ 1.704 Reduction of period of adjustment of patent term.

* * * * *

(c) * * *

(11) Failure to comply with § 1.75(b), in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date that is the later of the filing date of the amendment resulting in the non-compliance with § 1.75(b), or four months from the filing date of the application in an application under 35 U.S.C. 111(a) or from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) in an application which entered the national stage from an international application after compliance with 35 U.S.C. 371, and ending on the date that an examination support document in compliance with § 1.265, an election in reply to a requirement under § 1.142(a), 1.146 or 1.499 resulting in compliance with § 1.75(b), an amendment resulting in compliance with § 1.75(b), or a suggested restriction requirement in compliance with § 1.142(c), was filed;

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Dated: August 2, 2007.

Jon W. Dudas,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

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